

# HOUSE OF REPRESENTATIVES—Monday, April 5, 1993

The House met at 12 noon.

The Chaplain, Rev. James David Ford, D.D., offered the following prayer:

Our prayers are words of celebration and acclamation for blessings in days past and our prayers today are words of petition for the time before us. O gracious and loving God, You have been our strength in all the generations and our hope for years to come, be our guardian and guide in all we do so Your spirit will be with us and bless us until the day's end and the shadows flee away and we are at rest. Amen.

## THE JOURNAL

The SPEAKER. The Chair has examined the Journal of the last day's proceedings and announces to the House his approval thereof.

Pursuant to clause 1, rule I, the Journal stands approved.

## PLEDGE OF ALLEGIANCE

The SPEAKER. The Chair recognizes the gentleman from Michigan [Mr. KILDEE] to lead us in the Pledge of Allegiance.

Mr. KILDEE led the Pledge of Allegiance as follows:

I pledge allegiance to the Flag of the United States of America, and to the Republic for which it stands, one nation under God, indivisible, with liberty and justice for all.

## COMMUNICATION FROM CHAIRMAN AND RANKING MEMBER OF COMMITTEE ON HOUSE ADMINISTRATION

The Speaker laid before the House the following communication from the chairman and ranking member of the Committee on House Administration:

COMMITTEE ON HOUSE ADMINISTRATION,  
Washington, DC, March 31, 1993.

Hon. THOMAS S. FOLEY,  
Speaker, House of Representatives,  
The Capitol, Washington, DC.

DEAR MR. SPEAKER: Pursuant to the authority vested in the Committee on House Administration by House Rule X, Clause 4(d)(3), and upon recommendation of the Subcommittee on Administrative Oversight of the Committee on House Administration pursuant to Clause 3(j)(2), the Committee has directed the following, effective on April 1, 1993:

The responsibility for the operation of the House Office Furnishings, the House Office Supply Service, and the House Office Systems Management activities is transferred to the Director of Non-Legislative and Financial Services, subject to the oversight of the Subcommittee on Administrative Over-

sight of the Committee on House Administration.

It is intended, to the extent applicable, that the House Office Furnishings, the House Office Supply Service, and the House Office Systems Management offices continue to operate under the existing statutory authority of the Clerk of the House, but at the direction of the Director of Non-Legislative and Financial Services, until such time as the necessary statutory changes are enacted.

Pursuant to the House Employees Position Classification Act, 2 USC §291 et seq., the Committee further directs:

The following positions are transferred from the Office of the Clerk to the Office of the Director of Non-Legislative and Financial Services:

Position and grade: 1 assistant to the clerk, HS 15; 1 secretary, HS 06.

Upon receipt of a copy of this letter, the Clerk of the House is directed to continue to carry out the ministerial functions imposed by statute with regard to the operation of the House Office Furnishings, the House Office Supply Service, and the House Office Systems Management offices subject to the direction of the Director of Non-Legislative and Financial Services, and to continue to work cooperatively with the Director and the Subcommittee on Administrative Oversight of the Committee on House Administration to ensure that all functions and operations of these offices are timely executed.

Sincerely,

CHARLIE ROSE,  
Chairman.

WILLIAM M. THOMAS,  
Ranking Republican  
Member.

## APOLOGY TO GENZYME, INC., FOR OVERSTATING CURRENT PROFITS FROM ORPHAN DRUGS

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from California [Mr. STARK] is recognized for 5 minutes.

Mr. STARK. Mr. Speaker, I would like to correct a statement made upon introduction of the Orphan Drug Amendments Act of 1993.

In identifying the profitability of the product Ceredase, the distinction between projected profits and current profits was not made. This is an important distinction and I apologize for the mistake.

Using data drawn from an Office of Technology Assessment [OTA] report, calculations were made regarding the projected profitability of the Genzyme, Inc., product Ceredase. As reported in the OTA study, between 2,100 and 11,000 people in the United States suffer from gaucher's disease. Ceredase is sold at a retail price of \$3.50 per unit. The cost of manufacturing, marketing, and distributing Ceredase is reported to be \$1.90 per unit. According to the OTA, depending upon the treatment dose employed, a year of therapy can cost between \$71,160 to \$552,760.

Multiplying the midpoint of the estimated number of potential beneficiaries, 6,550 by the price of the most conservative treatment regime identified, \$71,160 and factoring out the cost of manufacturing, marketing, and distribution—\$1.90 of the \$3.50 per unit price, or \$0.54 per retail dollar—generates a projected \$214 million of revenues above the cost of manufacturing, marketing, and distribution.

Whether the 6,550 potential beneficiaries cited represents the annual number of Ceredase recipients or the total number of treatment years provided—roughly 800 patients in each of 8 years—the point is the same. The revenues generated in excess of the cost of production, marketing, and distribution are many times the initial investment of \$29 million. Windfall profits are being taken on this product.

Genzyme, Inc.'s pricing policy appears to be particularly excessive when compared against the extremely limited risk assumed by Genzyme, Inc. in the development of the product. I'd like to refer to my introductory statement to reiterate a point that should not be overlooked:

It was government-sponsored research that discovered the underlying defect causing Gaucher disease. It was government-sponsored research that devised a method for harvesting the enzyme to treat the disease. It was government-sponsored research that refined the harvesting procedure in order to greatly improve the effectiveness of the enzyme.

Using figures provided by one Wall Street pharmaceutical analyst, it is possible to make a similar estimation using the actual sales of Genzyme, Inc. last year. In 1992, total revenues were reported to be \$95 million from the sale of Ceredase. Applying the cost-to-price ratio calculated by the Office of Technology Assessment of .54:1, revenues in excess of costs in the neighborhood of \$40 million may have been generated from Ceredase patients in 1992 alone.

It is interesting to note that the \$95 million in revenues for 1992 were reported to be generated from a patient base of 800 people. This is an average of \$118,750 per Gaucher patient, or \$47,000 per patient more than that used in my calculations on the projected profitability of Ceredase. If this figure is employed rather than the more conservative estimate of \$71,160, the potential earnings from Gaucher disease would be increased substantially.

The design and goal of the amendments that I have proposed are to ensure a balance in the risk-reward equation employed in the development of orphan drugs. Whether we focus upon projected future sales or current sales, the point here is the same. This balance is currently not in place as some manufacturers are abusing the protections granted in the Orphan Drug Act.

□ This symbol represents the time of day during the House proceedings, e.g., □ 1407 is 2:07 p.m.

Matter set in this typeface indicates words inserted or appended, rather than spoken, by a Member of the House on the floor.

## SPECIAL ORDERS GRANTED

By unanimous consent, permission to address the House, following the legislative program and any special orders heretofore entered, was granted to:

(The following Members (at the request of Mr. INSLEE) to revise and extend their remarks and include extraneous material:)

Mr. WOLF, for 30 minutes, on April 20.  
Mr. CANADY, for 60 minutes, on April 20.

(The following Members (at the request of Mr. INSLEE) to revise and extend their remarks and include extraneous material:)

Mr. FIELDS of Louisiana, for 5 minutes, today.

Mr. STARK, for 5 minutes, today.

Mr. GONZALEZ, for 60 minutes, on April 12.

Mr. LARROCCO, for 30 minutes, today.

Mr. CONYERS, for 60 minutes each day, on April 28 and May 13.

## EXTENSION OF REMARKS

By unanimous consent, permission to revise and extend remarks was granted to:

(The following Members (at the request of Mr. INSLEE) and to include extraneous matter:)

Mr. ARCHER in two instances.

Mr. SOLOMON in two instances.

Mr. ROTH.

Mr. DICKEY.

Mr. RIDGE.

Mr. WELDON.

Mr. UPTON.

Mr. DREIER.

Mr. BEREUTER in two instances.

Mr. THOMAS of California.

Mr. BUNNING.

Mr. FRANKS of New Jersey.

Mr. CUNNINGHAM.

Mr. CRANE in two instances.

Mr. BATEMAN in two instances.

Mr. YOUNG of Alaska.

Mr. MYERS of Indiana.

Mr. HORN.

(The following Members (at the request of Mr. INSLEE) and to include extraneous matter:)

Mr. RICHARDSON in two instances.

Mr. TAUZIN.

Mr. KILDEE.

Mr. MAZZOLI in three instances.

Mr. BILBRAY.

Ms. HARMAN.

Mr. GEJDENSON.

Mr. JOHNSON of South Dakota.

Mr. ROEMER.

Mr. MILLER of California.

Mr. WILLIAMS.

Mr. SCHUMER in two instances.

Mr. HOYER.

Mr. KANJORSKI in two instances.

Mrs. MINK in two instances.

Mr. SWETT.

Mr. ANDREWS of Maine.

Mr. MOAKLEY.

Mr. POSHARD.

Mrs. COLLINS of Illinois.

Mr. ORTON.

Mr. MFUME.

Mr. PETERSON of Florida.

## ENROLLED BILLS SIGNED

Mr. ROSE, from the Committee on House Administration, reported that that committee had examined and found truly enrolled bills of the House of the following titles, which were thereupon signed by the Speaker:

H.R. 239. An act to amend the Stock Raising Homestead Act to resolve certain problems regarding subsurface estates, and for other purposes.

## ADJOURNMENT

Mr. INSLEE. Mr. Speaker, I move that the House do now adjourn.

The motion was agreed to; accordingly (at 12 o'clock and 6 minutes p.m.) under its previous order, the House adjourned until Wednesday, April 7, 1993, at 2 p.m.

## EXECUTIVE COMMUNICATIONS, ETC.

Under clause 2 of rule XXIV, executive communications were taken from the Speaker's table and referred as follows:

1017. A letter from the Chairman, Consumer Product Safety Commission, transmitting a report made by the Commission under section 37 of the Consumer Product Safety Act, pursuant to Public Law 101-608, section 112(f)(2) (104 Stat. 3117); to the Committee on Energy and Commerce.

1018. A letter from the Acting Director, Defense Security Assistance Agency, transmitting notice concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance [LOA] to France for defense articles and services (Transmittal No. 93-08), pursuant to 22 U.S.C. 2776(b); to the Committee on Foreign Affairs.

1019. A letter from the Acting Director, Defense Security Assistance Agency, transmitting notice concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance [LOA] to Japan for defense articles and services (Transmittal No. 93-10), pursuant to 22 U.S.C. 2776(b); to the Committee on Foreign Affairs.

1020. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting notification of a proposed license for the export of major defense equipment and services sold commercially to INTELSAT (Transmittal No. DTC-17-93), pursuant to 22 U.S.C. 2776(c); to the Committee on Foreign Affairs.

1021. A letter from the Comptroller General, General Accounting Office, transmitting a compilation of the summaries found in the monthly lists sent between October 1991 and September 1992, pursuant to 31 U.S.C. 719(h); to the Committee on Government Operations.

1022. A letter from the Executive Vice President, Tennessee Valley Authority, transmitting the statistical summaries as part of the TVA's annual report, covering the period beginning October 1, 1991, to September 30, 1992, pursuant to 16 U.S.C. 831h(a); to the Committee on Public Works and Transportation.

1023. A letter from the Director, Congressional Budget Office, transmitting the CBO's

Sequestration Preview Report for fiscal year 1994, pursuant to Public Law 101-508, section 13101(a) (104 Stat. 1388-587); jointly, to the Committees on Appropriations and the Budget.

## PUBLIC BILLS AND RESOLUTIONS

Under clause 5 of rule X and clause 4 of rule XXII, public bills and resolutions were introduced and severally referred as follows:

By Mr. INSLEE:

H.R. 1690. A bill to authorize certain elements of the Yakima River Basin Water Enhancement Project, and for other purposes; to the Committee on Natural Resources.

By Mr. ANDREWS of Maine:

H.R. 1691. A bill to provide universal access for all Americans to basic health care services and long-term care services; jointly, to the Committee on Energy and Commerce, Ways and Means, Education and Labor, Rules, Armed Services, Veterans' Affairs, and Post Office and Civil Service.

By Mr. ANDREWS of Texas:

H.R. 1692. A bill to renew until January 1, 1997, the previous suspension of duty on certain chemicals; to the Committee on Ways and Means.

H.R. 1693. A bill to reduce until January 1, 1997, the duty on certain chemicals; to the Committee on Ways and Means.

H.R. 1694. A bill to suspend until January 1, 1997, the duty on certain chemicals; to the Committee on Ways and Means.

By Mr. CARR:

H.R. 1695. A bill to amend the Internal Revenue Code of 1986 to increase and make permanent the deduction for the health insurance costs of self-employed individuals; to the Committee on Ways and Means.

By Mrs. MINK:

H.R. 1696. A bill to provide for the regulation of the airspace over National Park System lands in the State of Hawaii by the Federal Aviation Administration and the National Park Service, and for other purposes; jointly, to the Committee on Natural Resources and Public Works and Transportation.

By Mr. MONTGOMERY (for himself and Mr. GONZALEZ):

H.R. 1697. A bill to require the Secretary of the Treasury to mint coins in commemoration of the Women in Military Service for American Memorial; to the Committee on Banking, Finance and Urban Affairs.

By Mr. POSHARD:

H.R. 1698. A bill to prohibit Members of the House of Representatives from using official funds for the production or mailing of newsletters; to reduce by 50 percent the amount which may be made available for the Official Mail Allowance of any such Member; and for other purposes; to the Committee on House Administration.

By Ms. WATERS (for herself, Mr. RANGEL, Mr. MFUME, Mr. CLAY, Ms. NORTON, and Ms. MEEK):

H.R. 1699. A bill to provide assistance to community development lending institutions to increase the availability of credit to low-income families and for economic and community development and other activities in low-income neighborhoods, and for other purposes; to the Committee on Banking, Finance and Urban Affairs.

By Ms. WATERS (for herself, Mr. RANGEL, Mr. CLAY, Ms. NORTON, and Ms. MEEK):

H.R. 1700. A bill to amend the Community Reinvestment Act and the Home Mortgage

Disclosure Act of 1975 to improve the availability of credit on a nondiscriminatory basis; to the Committee on Banking, Finance and Urban Affairs.

By Mr. WAXMAN (for himself and Mr. DINGELL):

H.R. 1701. A bill to amend title XVI of the Public Health Service Act (the Safe Drinking Water Act) to establish State revolving funds to provide for drinking water treatment facilities, and for other purposes; to the Committee on Energy and Commerce.

By Mrs. MINK:

H.J. Res. 176. Joint resolution proposing an amendment to the Constitution of the United States protecting reproductive rights; to the Committee on the Judiciary.

#### ADDITIONAL SPONSORS

Under clause 4 of rule XXII, sponsors were added to public bills and resolutions as follows:

H.R. 502: Mr. GOSS, Mr. DOOLITTLE, Mr. ZIMMER, Mr. ROYCE, Mr. TORKILDSEN, Mr. BE-REUTER, and Mr. ZELIFF.

H.R. 503: Mr. STEARNS.

H.R. 579: Mr. UPTON and Mr. DINGELL.

H.R. 776: Mr. TAYLOR of North Carolina and Mr. FISH.

H.R. 786: Mr. SUNDQUIST.

H.R. 798: Mr. PENNY, Ms. WATERS, Mr. HEFNER, Mr. RICHARDSON, Mr. STENHOLM, Mr. PAYNE of Virginia, and Mr. PARKER.

H.R. 951: Ms. BYRNE and Mr. SISISKY.

H.R. 995: Mr. EVERETT, Mr. HEFNER, Mr. RICHARDSON, Mr. STENHOLM, Mr. PAYNE of Virginia, and Mr. PARKER.

H.R. 1032: Ms. WATERS.

H.R. 1158: Mr. BLACKWELL and Mr. BARRETT of Wisconsin.

H.R. 1286: Mr. BARRETT of Nebraska, Mr. PAYNE of Virginia, Mr. GOSS, Mr. MANZULLO, Mr. KIM, Mr. MURPHY, Mr. HASTINGS, Mr. ZIMMER, Mr. MOORHEAD, and Mr. HUTTO.

H.R. 1322: Mr. FRANKS of New Jersey.

H.R. 1456: Mr. BOEHNER, Mr. MCHUGH, Mr. FINGERHUT, Mr. WALSH, Mrs. CLAYTON, and Mr. DORNAN.

H.R. 1505: Mr. ZIMMER.

H.J. Res. 155: Mr. MANN, Mr. FISH, Mr. ROHRBACHER, Mr. SUNDQUIST, Mr. LIPINSKI, Mr. STARK, Mr. JEFFERSON, Mr. PETERSON of Minnesota, Mr. GILLMOR, Mr. VOLKMER, Mr. SHARP, Mr. MYERS of Indiana, Mr. BURTON of Indiana, Mr. MCCLOSKEY, Mr. ROEMER, and Mr. JACOBS.

H. Con. Res. 38: Mr. ACKERMAN, Mr. ENGEL, Ms. MEEK, Mr. LEVY, and Mr. MCCURDY.

H. Con. Res. 69: Mr. MCHUGH, Mrs. MINK, Mr. RAHALL, Mr. RICHARDSON, Mr. ROGERS, Mrs. VUCANOVICH, Mr. WILSON, Mr. CLINGER, Mr. SWETT, Mr. SISISKY, Mr. CAMP, Ms. DANNER, Mr. BREWSTER, Mr. MANZULLO, Mr. POMEROY, Mr. BARCIA Mr. HAYES of Louisiana, Mr. RIDGE, Mr. SKEEN, Mr. SPENCE, Mr. KOPETSKI, Mrs. UNSOELD, Mr. PAYNE of Virginia, Mr. STRICKLAND, Mr. DEFazio, Mrs. CLAYTON, Mr. SANDERS, and Mr. VOLKMER.

H. Con. Res. 74: Mr. WALSH, Mr. TORKILDSEN, and Mr. INGLIS.

H. Res. 134: Mr. FRANKS of New Jersey, Mr. MCKEON, Mr. LAZIO, and Mr. KNOLLENBERG.

H. Res. 135: Mr. JACOBS.